MAY 2 2000

NDA 00-793/S-20

Wallace Laboratories, Division of Carter-Wallace, Inc.
Attention: Ana M. Fontana
Vice President Drug Regulatory Affairs
Half Acre Road
P.O. Box 1001
Cranbury, NJ 08512-0181

Dear Ms. Fontana:

Please refer to your supplemental new drug application dated August 27, 1998, received August 28, 1998, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Butisol Sodium® (butabarbital sodium, USP) Tablets.

This "Changes Being Effected" supplemental new drug application provides for the following:

- A Geriatric Use subsection was incorporated in the labeling to strengthen the precautions information for the safe use of the drug.
- The storage temperature statement was revised in accordance with the current United States Phannacopoeia (USP) and the September 1994 International Conference on Harmonisation (ICH) Stability Guidelines.
- The prescription drug legend and the habit-forming drug warning statement have been removed from the labeling, in accordance with the provisions of the FDA Modernization Act of 1997 (FDAMA).
- References to the 100 mg tablets, which have been discontinued, have been deleted from the labeling.

We have completed the review of this supplemental new drug application, and have concluded that adequate information has been presented to demonstrate that the drug is safe and effective for use as recommended in the final printed labeling submitted on August 27, 1998.

Accordingly, the supplemental new drug application is approved effective on the date of this letter.

If a letter communicating important information about this drug product (i.e., a "Dear Health Care Practitioner" letter) is issued to physicians and others responsible for patient care, we request that you submit a copy of the letter to this NDA and a copy to the following address:

MED WATCH, HF-2
FDA
5600 Fishers Lane
Rockville, MD 20857

We remind you that you must comply with the requirements for an approved NDA set forth under 21 CFR 314.80 and 314.81.

If you have any questions, please call Ms. Melaine Shin, R.Ph., Regulatory Management Officer, at (301) 594-5511.

Sincerely,

Russell Katz, M.D.
Director
Division of Neuropharmacological Drug Products
Office of Drug Evaluation I
Center for Drug Evaluation and Research

Geriatric use: Clinical studies of Butisol Sodium Tablets/Elixir did not include sufficient numbers of subjects aged 65 and over to determine whether they respond differently from younger subjects. Other reported clinical experience has not identified differences in responses between the elderly and younger patients. In general, dose selection for an elderly patient should be cautious, usually starting at the low end of the dosing range, reflecting the greater frequency of decreased hepatic, renal, or cardiac function, and of concomitant disease or other drug therapy.